NIH ACTIV THERAPEUTICS CLINICAL TRIALS

I. Overview and Updates

II. Host Tissue-Directed Therapeutics

NIH Advisory Council to the Director
Briefing

December 9, 2021

Rising to the Public Health Challenges of COVID-19 and Beyond: Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

VISIONARY LEADERSHIP

Providing partnership, dedication, and support to ACTIV Therapeutic Clinical Enterprise

Francis Collins, M.D., Ph.D.

Paul Stoffels, M.D.

- Unparalleled public-private partnership
- Collaborative forum to identify most promising interventions and accelerate clinical testing
  - Launch and open sharing of master protocols for evaluating candidates
  - Improve clinical trial capacity/effectiveness by leveraging infrastructure and expertise from across NIH and non-NIH networks and CROs
- Accelerate evaluation of vaccine candidates to enable rapid authorization or approval
- Identify emerging variants and coordinate data sharing (TRACE WG)
- Unprecedented data sharing between academia and industry

→ **ACTIV enterprise provides pathway and model for future preparedness efforts**

NIH ACTIV THERAPEUTICS CLINICAL TRIALS: AT-A-GLANCE

ENROLLMENTS & ACTIVATION

13,813 Patients enrolled into ACTIV trials

700+ Sites in partnership with **multiple networks** including ACTG, CONNECTS, DCRI, INSIGHT, PETAL, CTSN, PCORnet, CTSA, IDeA Sites, ACTT, and others

PUBLICATIONS

17 Scientific Publications on ACTIV Trials released in **7 Medical Journals**

These publications have been **cited 478 times** (*Google Scholar*)

AGENT REVIEWS & AUTHORIZATIONS

800+ Total agents reviewed by ACTIV Tx-Clinical and CONNECTS WGs Agent Review Panels

15 Agents fully enrolled and completed testing through the ACTIV Master Protocols

4 Agents proven efficacious against COVID-19 in analysis of data from ACTIV Trials.
Other priority agents being tested

- **EUA ACHIEVEMENTS:**
  - Lilly monoclonal approval
  - Brii Bio rolling submission
  - AZ applying for EUA intending to have ACTIV outpatient data noted in the submission package
- Both the **Merck and Pfizer compounds** being assessed for EUA were originally selected for testing in ACTIV trials
- ACTIV-4 work on heparin and other anticoagulants **changed clinical practice**

NIH ACTIV THERAPEUTICS MASTER PROTOCOL DESCRIPTIONS

Master Protocol	Protocol Description	Current Trial Status
ACTIV-1	• Inpatient, RCT, Double-blind Phase III Master Protocol • Host-targeted Immune Modulators • NCATS TIN + DCRI + TRI + CRO • Target Sample Size (Patients per Arm): 540	***Trial launched on October 16, 2020*** • Agent(s) being tested: Abatacept, Cenicriviroc, Infliximab
ACTIV-2	• Outpatient, RCT, Double-blind Phase II/III Master Protocol • Neutralizing Monoclonal Antibodies (nMABs) and Oral Antivirals • NIAID ACTG + CRO • Target Sample Size (Patients per Arm): 110 [Phase II] & 600 [Phase III]	***Trial launched on August 3, 2020*** • Agent(s) being tested: nMABs (Lilly, Brii Bio, RU-BMS), IFN-beta (Synairgen), camostat (Sagent), nPAB (SAB)
ACTIV-3	• Inpatient, RCT, Double-blind Phase III Master Protocol • Neutralizing Monoclonal Antibodies and other (e.g., protease inhibitor) • NIAID INSIGHT + NHLBI PETAL + NHLBI CTSN + VA + CRO • Target Sample Size (Patients per Arm): 500	***Trial launched on August 4, 2020*** • Agent(s) being tested: nMABs (Lilly, Brii, GSK-Vir, AZ), DARPin (Molecular Partners), protease inh. (Pfizer)
ACTIV-3B	• Inpatient, RCT, Double-blind Phase III Master Protocol • Host-targeted Immune Modulators • NIAID INSIGHT + NHLBI PETAL + NHLBI CTSN + VA + CRO • Target Sample Size (Patients per Arm): 310	***Trial launched on April 21, 2021*** • Agent(s) being tested: Aviptadil (VIP) (NeuroRX) • Agents in the Pipeline: Immune Modulators for ARDS

NIH ACTIV THERAPEUTICS MASTER PROTOCOL DESCRIPTIONS

Master Protocol	Protocol Description	Current Trial Status
ACTIV-4A	• Inpatient, Pragmatic, Randomized, Open Label Phase III Master Protocol • Host-tissue Directed Therapeutics including Anticoagulants, Anti-platelet, other Anti-thrombotics • NHLBI CONNECTS Network • Target Sample Size (Patients per Arm): 1000	***Trial launched on September 17, 2020*** • Agent(s) being tested: LMWH, UFH, P2Y12 Inhibitors (Anti-platelet Agents);
ACTIV-4B	• Outpatient, Randomized, Double-blind Phase III Master Protocol • Host-tissue Directed Therapeutics: Anticoagulants, Anti-platelet, other Antithrombotics • NHLBI CONNECTS Network • Target Sample Size (Patients per Arm): 1750	***Trial launched on September 17,2020*** • Agent(s) being tested: Low-dose Aspirin, Prophylactic-dose Apixaban, Therapeutic-dose Apixaban
ACTIV-4C	• Outpatient, Convalescent, RCT, Double-blind Phase III Master Protocol • Host-tissue Directed Therapeutics: Anticoagulants, Anti-platelet, other Antithrombotics • NHLBI CONNECTS Network • Target Sample Size (Patients per Arm): 2660	***Trial launched on February 9, 2021*** • Agent(s) being tested: Apixaban
ACTIV-4HT	• Inpatient, Pragmatic, Randomized, Open Label Phase II/III Master Protocol • Host-tissue Targeted Therapies (Most focusing on RAAS Pathway Regulation) • NHLBI CONNECTS Network • Target Sample Size (Patients per Arm): 300+	***Trial launched on July 2021*** • Agent(s) being tested: TXA127, TRV027, Fostamatinib

NIH ACTIV THERAPEUTICS MASTER PROTOCOL DESCRIPTIONS

Master Protocol	Protocol Description	Current Trial Status
ACTIV-5	• Inpatient, Randomized, Double-blind Phase II Master Protocol • Proof of Concept Study to Identify Promising Immuno Modulators • NIAID + CRO • Target Sample Size (Patients per Arm): 500	***Trial launched on October 9, 2020*** • Agent(s) being tested: Risankizumab, Lenzilumab, Danicopan
ACTIV-6	• Outpatient, RCT, Double-blind Phase III Master Protocol • Existing Prescription and Over-the-counter Medications • NCATS + DCRI + PCORnet + SignalPath + CRO • Target Sample Size (Patients per Arm): 300	***Trial launch on July 1, 2021*** • Agent(s) being tested: Ivermectin, fluvoxamine, fluticasone

Status Summary of ACTIV Agents: Completed and Currently Under Study

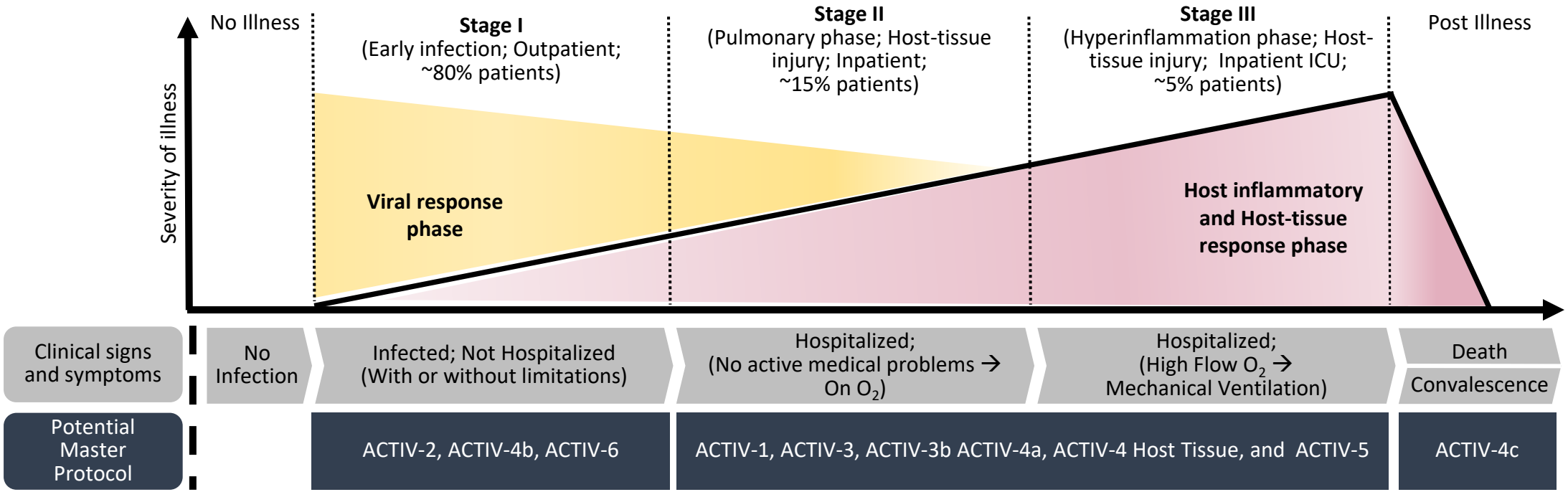
	Enrolling But Not Yet Reviewed for Efficacy / Futility	Ceased Enrollment (due to futility / low clinical value)	Continuing Enrollment (i.e., passed interim futility assessment)	Completed Enrollment
ACTIV-1		• Cenicriviroc	• Infliximab • Abatacept	
ACTIV-2/2B		• AZD7442 (IM)* • AZD7442 (IV)* • Camostat Mesylate • BMS-986414/BMS-986413	• SAB-185 • SNG001 IFN-beta	• Brii-196/Brii-198 • LY-CoV-555
ACTIV-3/3B	• Aviptadil and/or Remdesivir • Pfizer PF-07304814	• LY-CoV-555 • Brii-196/Brii-198 • VIR-7831 • DARPin MP0420		• AZD7442 (IV) *(awaiting topline data)*
ACTIV-4A		• Therapeutic Heparin and P2Y12 Inhibitors in Moderately-ill Pts	• Prophylactic Heparin and P2Y12 Inhibitors in Critically-ill Pts	• Un-fractionated and Low Molecular Weight Heparin
ACTIV-4B		• Aspirin • Apixaban		
ACTIV-4C			• Apixaban	
ACTIV-4HT	• TXA127 • TRV027 • Fostamatinib			
ACTIV-5	• Danicopan		• Lenzilumab	• Risankizumab *(awaiting topline data)*
ACTIV-6	• Fluvoxamine • Fluticasone		• Ivermectin	

**Enrollment ceased at company's request*

***Denotes** agent lack of efficacy*

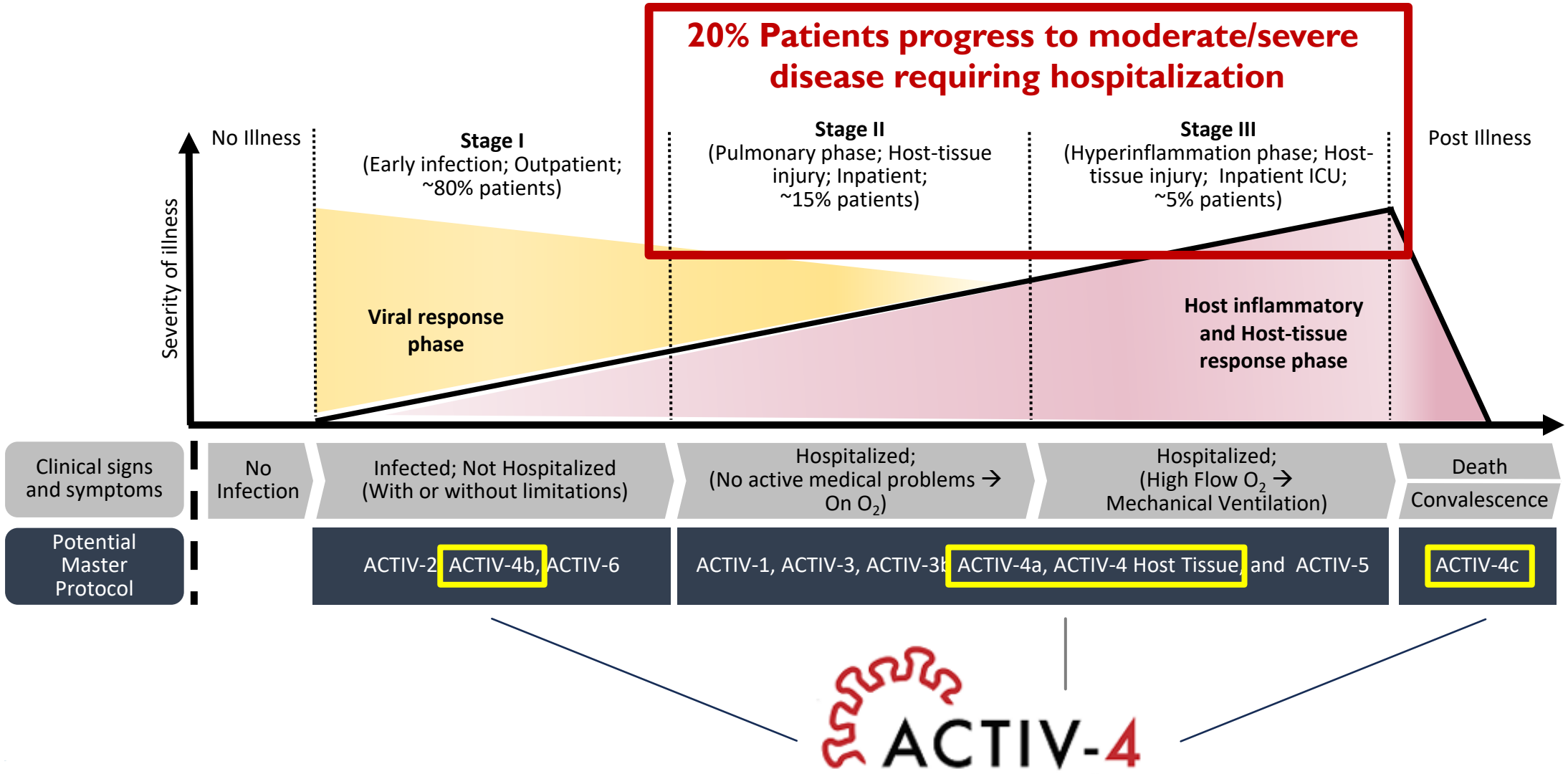
***Denotes** proven agent efficacy*

NIH ACTIV CLINICAL TRIALS TARGETING STAGES OF DISEASE



Iterative learning process: Determining which therapeutic strategies work/don't work in which clinical setting/stage of disease/patient group

NIH ACTIV CLINICAL TRIALS TARGETING STAGES OF DISEASE

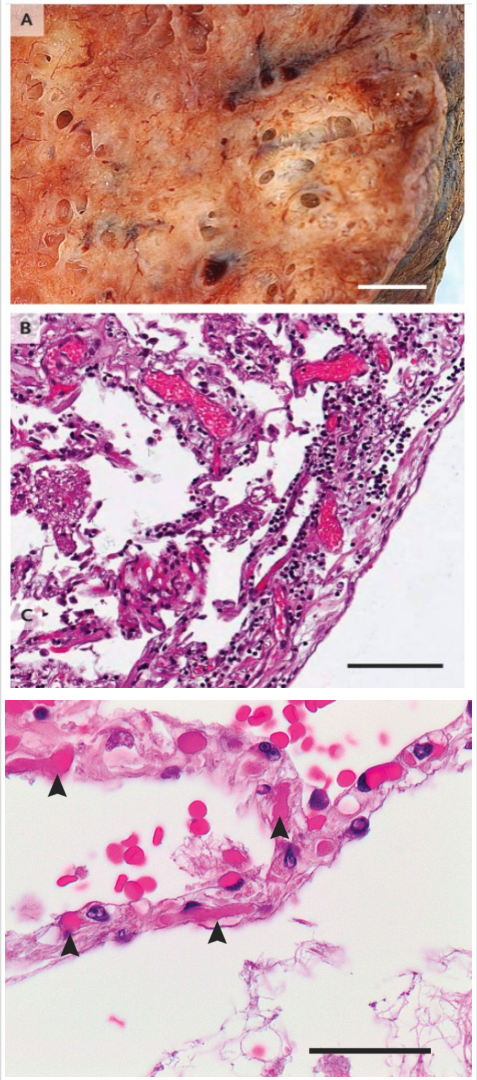


Host Tissue-Directed Therapeutics: A Critical Component of COVID-19 and Pandemic Preparedness Armamentarium

- **Majority (~80%) of SARS-CoV-2 infected patients experience mild to moderate symptoms** resolving w/in 6–10 days
- **~20% of patients develop severe illness** w/ typical interstitial bilateral pneumonia and ARDS; associated w/high fatality rate
- **Progression to more severe disease due to multi-tissue/organ dysfunction**
  - Endothelial dysfunction, systemic coagulopathy and complement-induced thrombosis with development of systemic microangiopathy and thromboembolism
- **Host tissue and organ targets:** lung epithelium, vascular endothelium, brain, kidney, gut, heart, and eye (among others)
- **Therapeutic interventions targeting host-tissue responses are a critical** complement to direct anti-virals and passive immune strategies

Illustrations credit: Anna & Elena Balbusso https://magazine.ucsf.edu/we-thought-it-was-just-respiratory-virus

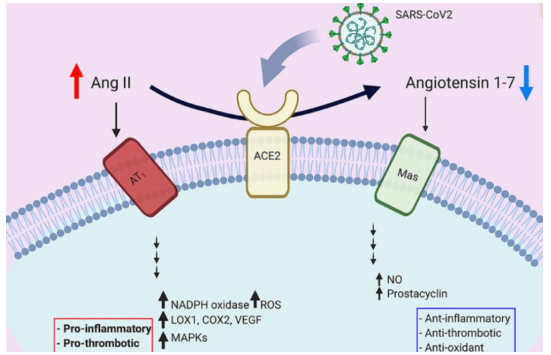
COVID-19 MULTI-TISSUE/MULTI-ORGAN INJURY: PATHOGENIC PATHWAYS

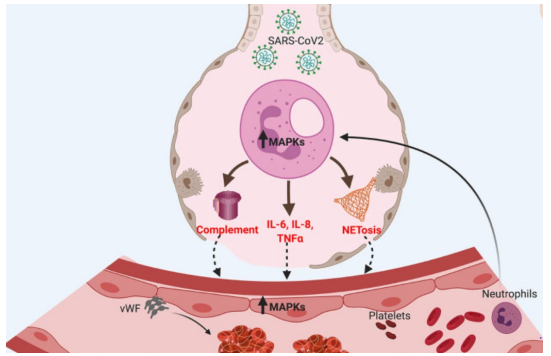


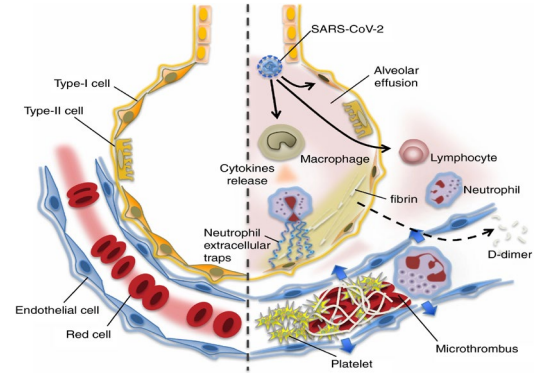
Host-tissue example: Lung

Histology: N Engl J Med 2020; 383:120-128

- Progressive COVID-19 characterized by severe inflammatory response, hypoxia, multi-tissue/organ injury due to direct and indirect viral mediated effects; high endothelial cell expression of ACE2
  - Vascular endotheliopathy and prothrombotic/coagulant state with high rates of thrombotic complications
- Poor prognosis consistently associated with dysregulation of:
  - **Renin-angiotensin-aldosterone system (RAAS)** leading to oxidative stress, vasoconstriction, endothelial dysfunction, release of P-selectin, and vWF activation
  - **Immune response** activating complement, neutrophil extracellular traps, and mitogen activated protein kinase pathways
  - **Coagulation cascade, thrombosis, and fibrinolysis** throughout macro- and microvasculature







Trends Cardiovasc Med. 2021 Apr; 31(3): 143–160.
Published online 2020 Dec 16. doi: 10.1016/j.tcm.2020.12.004

nternational Journal of Laboratory Hematology, Volume: 43, Issue: S1, Pages: 29-35, First published: 20 July 2021, DOI: (10.1111/ijlh.13500)

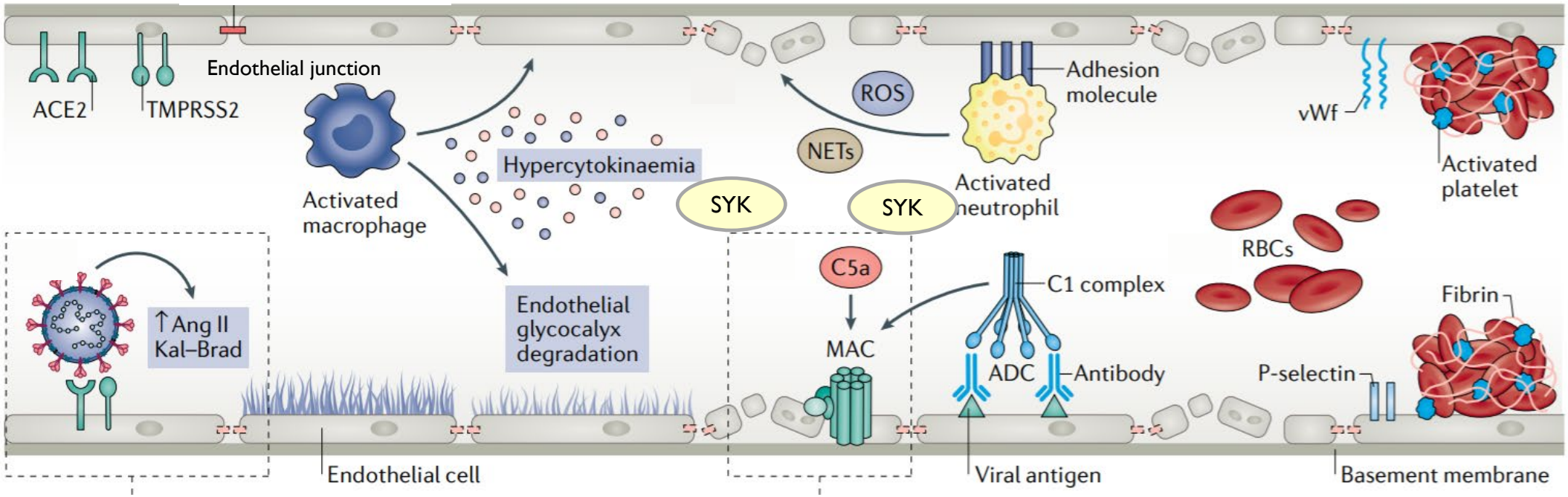
ACTIV-4 Host Tissue-Directed Therapeutics

Targeting Host-tissue Dysfunction Following SARS-CoV-2 Infection

Target:

RAAS Dysregulation | **Vascular Immuno-Thrombo-Inflammation Response** | **Hyper-Coagulation**

Inflammation | Hypoxia | Fibrosis | Capillary Leak | Pro-coagulant state | Hypo-fibrinolysis



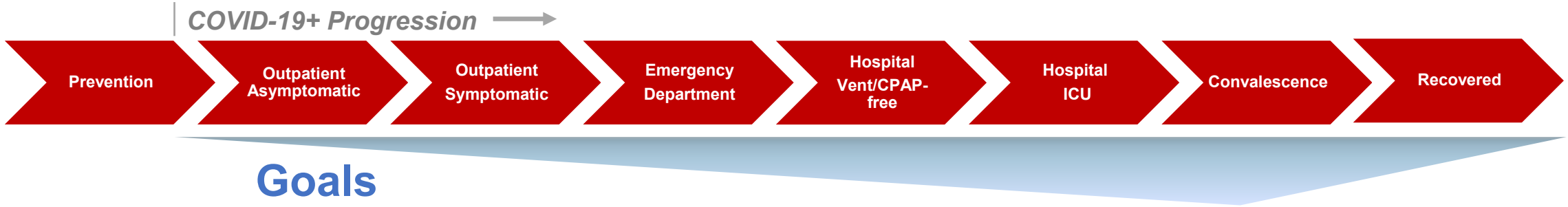
RAAS Agents (TXA127, TRV027)

Fostamatinib

Heparin, DOAC, ASA, P2Y12 inhibitors

Adapted from: Nature Reviews, Nephrology. (17): 46-64, 2021..

NHLBI COVID-19 Clinical Research Framework



Goals

Reduce case severity/fatality, speed recovery	→ Host-Directed Therapeutics Clinical Trials
Identify biomarkers and therapeutic targets	Integrated pathobiology/mechanistic studies
Enable risk stratification, precision interventions	→ Screening, Referral and Registries
Understand short- and long-term trajectory	Cohort of Cohorts for Long-Term Follow up
Target populations most severely affected	→ Community-Engaged Research Consortium

CONNECTS

"Collaborating Network of Networks for Evaluating COVID-19 and Therapeutic Strategies"

Goal: Leverage and expand NHLBI's national clinical research networks to rapidly and nimbly respond to emerging research and clinical needs for COVID-19

- **Part of NIH ACTIV**
- **Collaboration with NINDS, other ICs**
- **Leveraging existing assets**, data and studies and **forging new partnerships**
- Comprehensive, **expandable platform** linking trial network, registries, mechanistic studies, and cohorts
- Facilitating case finding, **clinical trial accrual**, **longitudinal studies, and community engagement**

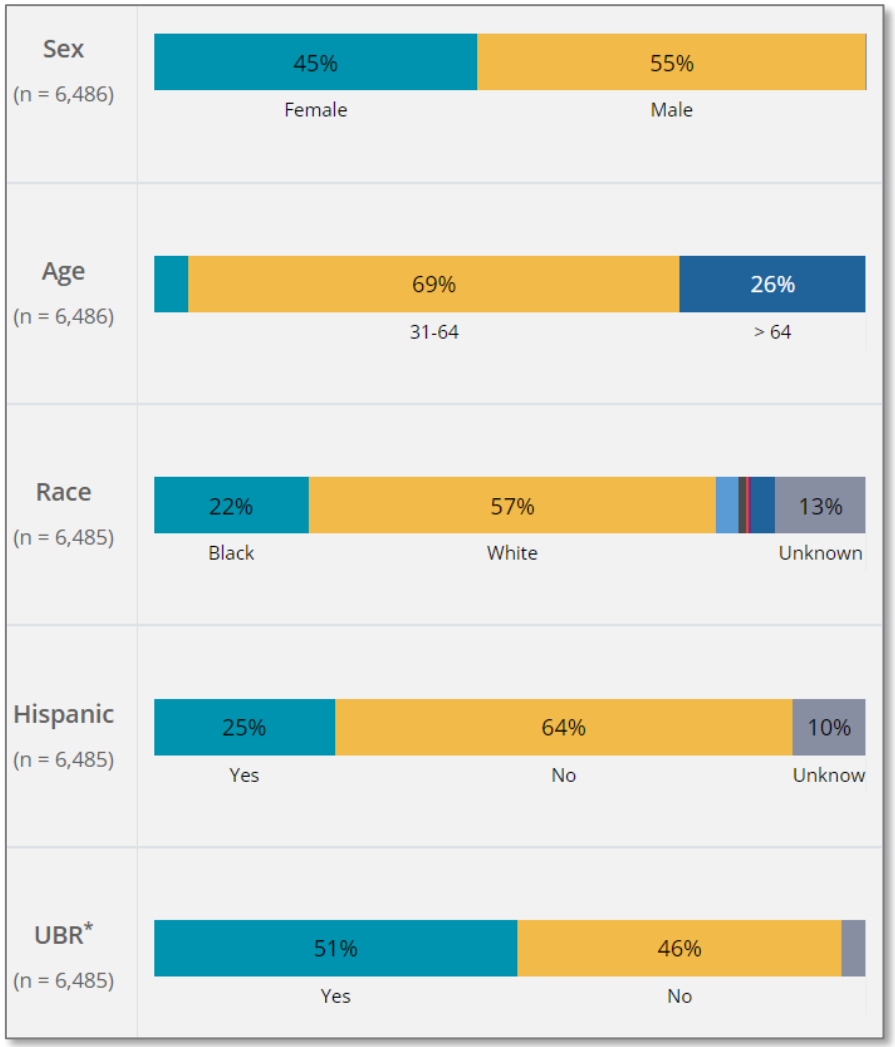
~300+ sites, ~ 6,500 ppts in clinical trials,
~58,000 ppts in longitudinal studies

ENGAGEMENT AND PARTICIPATION OF DIVERSE POPULATIONS

Enriching enrollment of disproportionately affected communities by leveraging community-engagement, multi-disciplinary partnerships across the NIH, and collaboration with patient groups

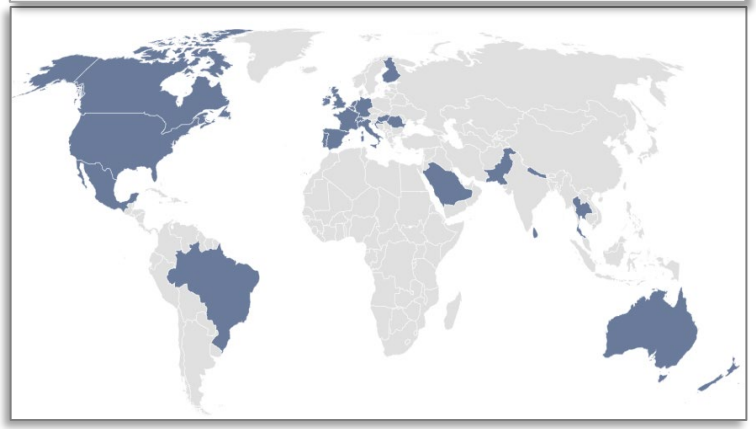
	% U.S. Population[1]	% U.S. COVID Cases[2]	% Ppts in CONNECTS Clinical Trials
Hispanic / Latinx	18.5	27.3	25
Black	13.4	16.4	22
Asian	5.9	2.4	3
Native Hawaiian & Pacific Islander	0.2	0.5	0
American Indian / Alaska Native	1.3	1.4	1

[1]United States Census Bureau (2019) [2]Hollis et al. (2021)

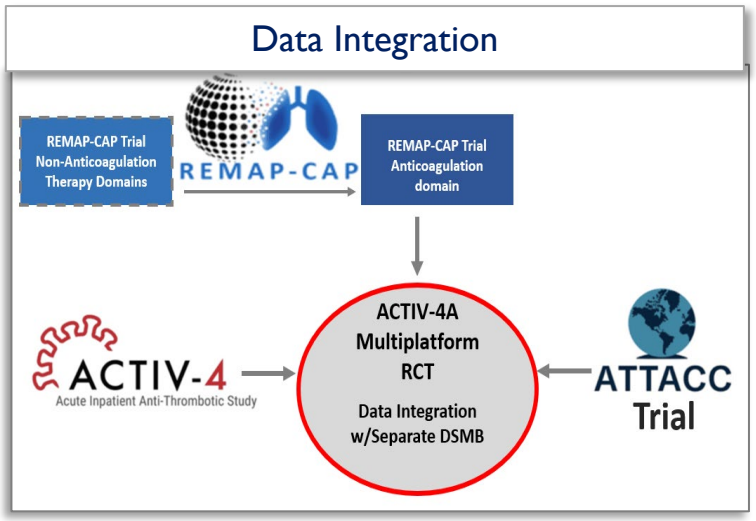


HOST TISSUE-DIRECTED CLINICAL TRIAL PLATFORM STRATEGY

International Collaboration

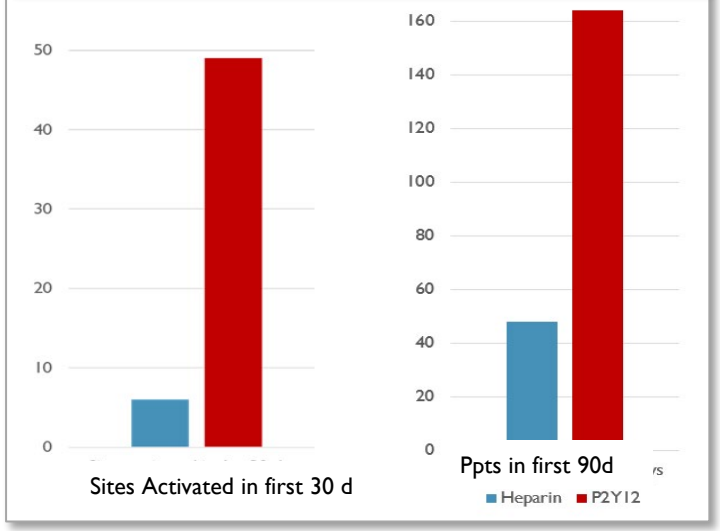


Data Integration

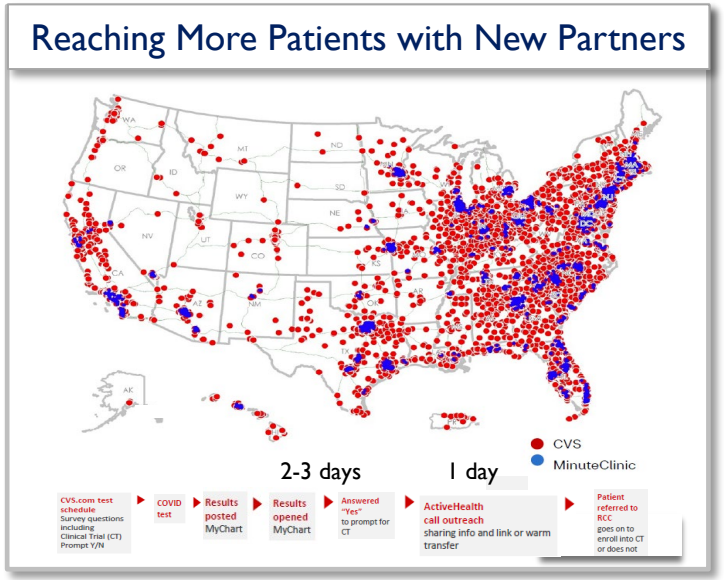


- **Collaborating with and leveraging international studies** examining same classes of agents:
  - Data integration
  - DSMB collaboration
- **Learning system: e.g., strategies to enhance trial start up and completion:**
  - 10-fold increase # sites activated and 4-fold increase # participants
  - Reaching more patients through new partners: Outreach through local pharmacies (e.g., CVS)

Accelerating Start-up and Enrollment



Reaching More Patients with New Partners



ACTIV-4A: A Phase III Multicenter, Adaptive, Randomized Controlled Platform Trial of the Safety and Efficacy of Antithrombotic and Additional Strategies in Hospitalized Adults with COVID-19

Prevention | Outpatient Asymptomatic | Outpatient Symptomatic | Emergency Department | **Hospital Vent/CPAP-free** | **Hospital ICU** | Convalescence | Recovered

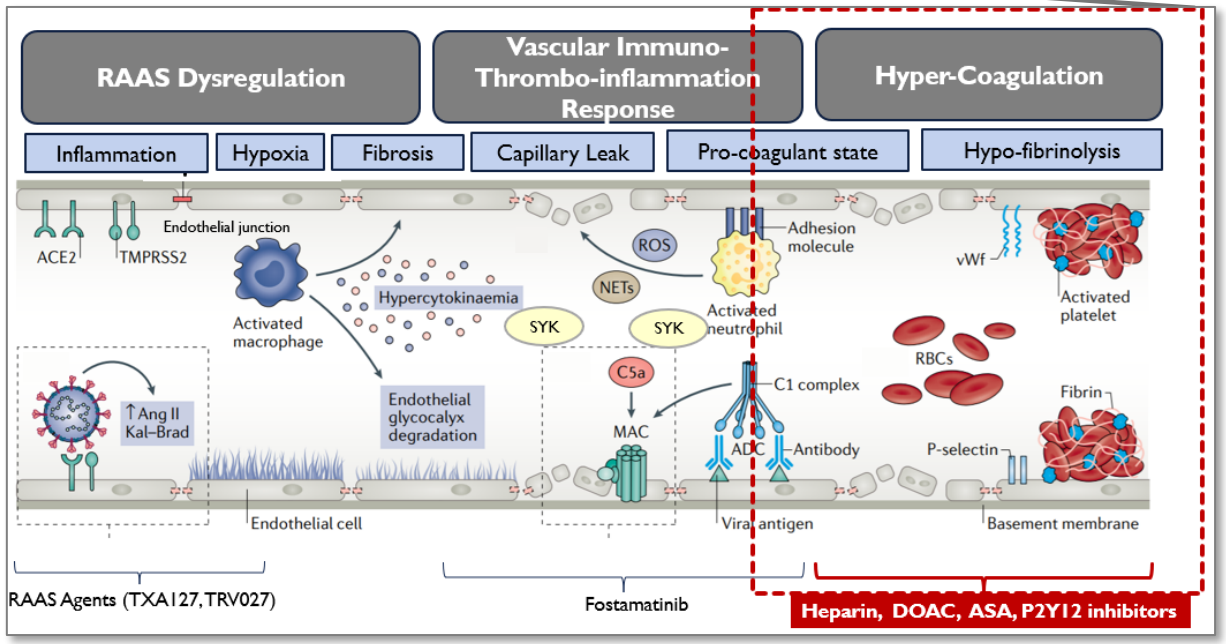
Patient Population: Moderately and severely ill hospitalized patients (+/- ventilatory support)

Interventions/Agents: Heparin, P2Y12 Inhibitors; (Planned: P-Selectin inhibitor (Crizanlizumab,) SGLT2 Inhibitor)

Primary Endpoint: Organ Support Free Days (OSFD)

Secondary Endpoints:

- Death, respiratory support, cardiovascular support, renal replacement therapy
- Composite endpoint (discharge or 28 days, whichever occurs first):
  - Death, PE, systemic arterial thromboembolism, MI, ischemic stroke
- Other Secondary Endpoints:
  - Acute kidney injury, 1˚ & 2˚endpoint components, death during hospitalization, WHO clinical scale, 90-day mortality



Does targeting the pro-thrombotic/pro-coagulant state and endotheliopathy of COVID-19 improve clinical outcomes for hospitalized patients?

ACTIV-4A: A Multicenter, Adaptive, Randomized Controlled Platform Trial of the Safety and Efficacy of Antithrombotic and Additional Strategies in Hospitalized Adults with COVID-19

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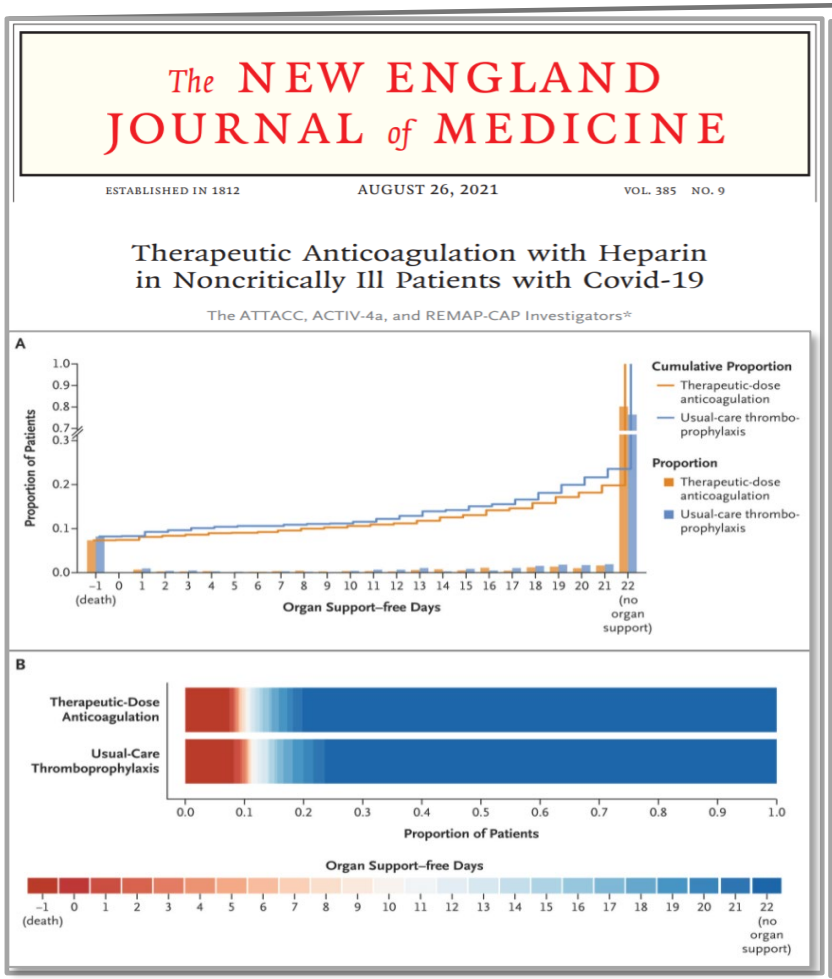
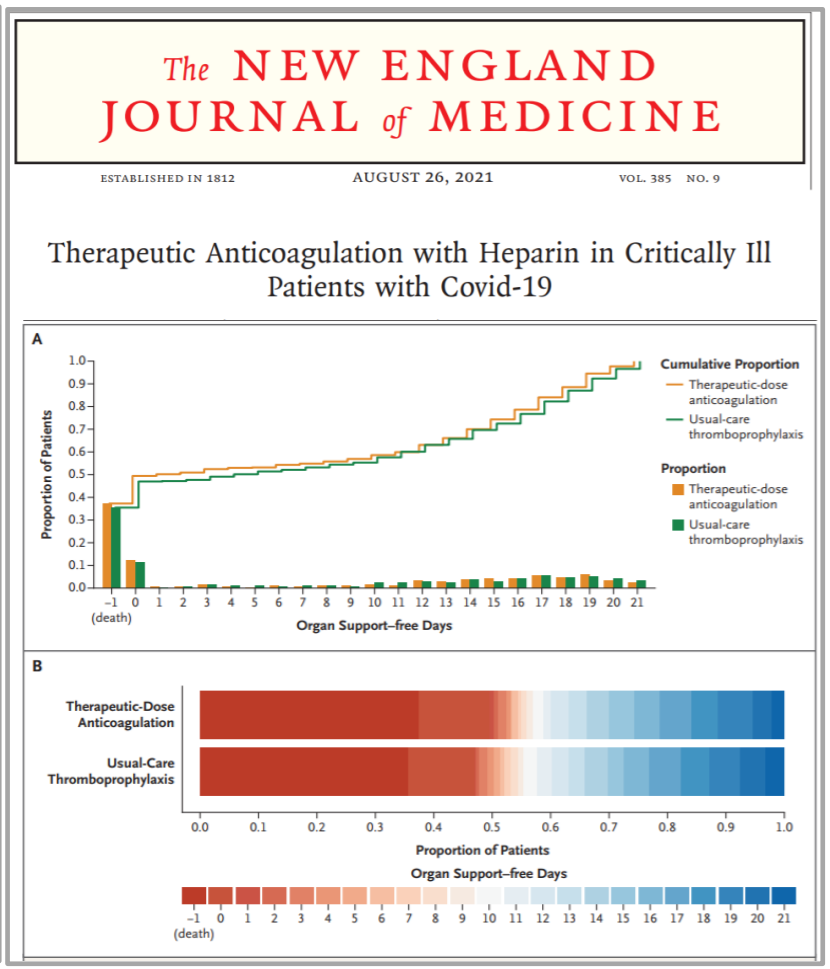

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 26, 2021 VOL. 385 NO. 9

Therapeutic Anticoagulation with Heparin in Noncritically Ill Patients with Covid-19

The ATTACC, ACTIV-4a, and REMAP-CAP Investigators*


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 26, 2021 VOL. 385 NO. 9

Therapeutic Anticoagulation with Heparin in Critically Ill Patients with Covid-19

Intervention: Prophylactic or therapeutic dose Heparin

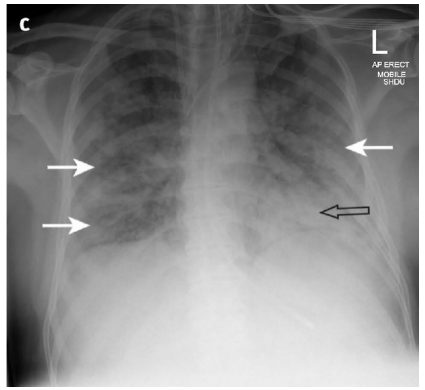
Therapeutic-dose anti-coagulation improved survival without need for organ support in moderately ill (non-critical) hospitalized patients but not in critically ill patients

https://www.nejm.org/doi/full/10.1056/NEJMoa2105911; https://www.nejm.org/doi/full/10.1056/NEJMoa2103417

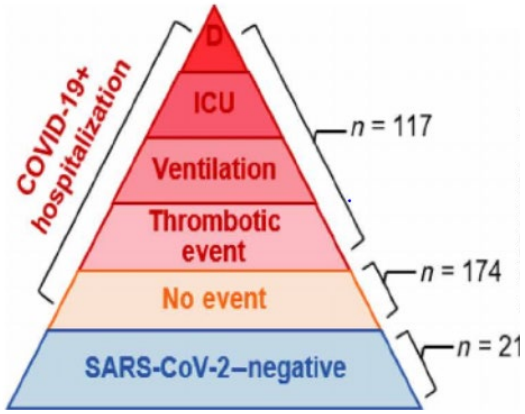
Science Advances | AAAS
SIGNIFICANT RESEARCH, GLOBAL IMPACT
Barrett et al., Sci. Adv. 2021; 7

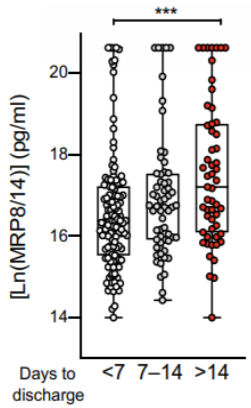
CONNECTS

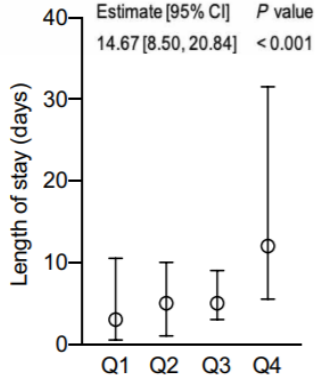
Mechanistic Studies in Parallel with Clinical Trials Inform Risk Stratification and New Targets

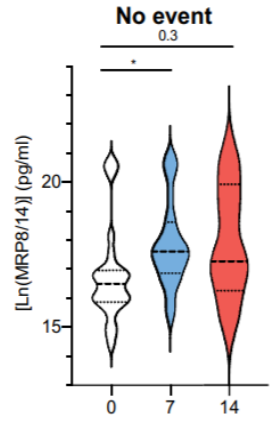


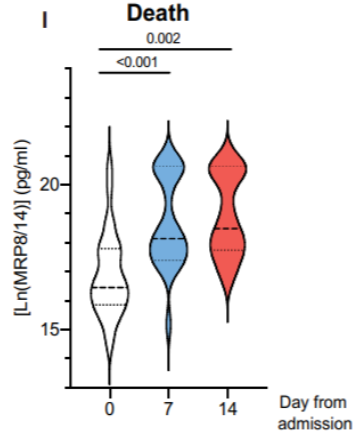
Chest X-Ray: BMJ 2020;370:m2426
http://dx.doi.org/10.1136/bmj.m2426

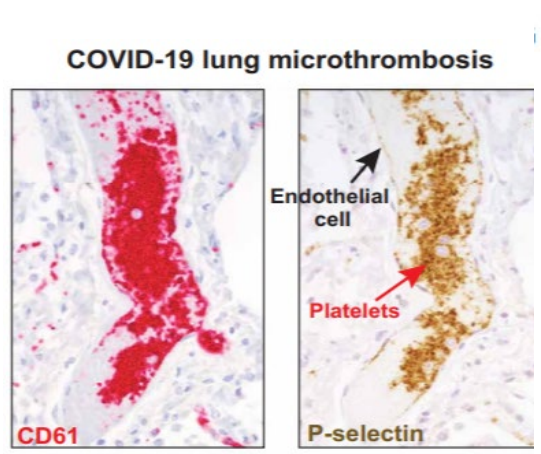


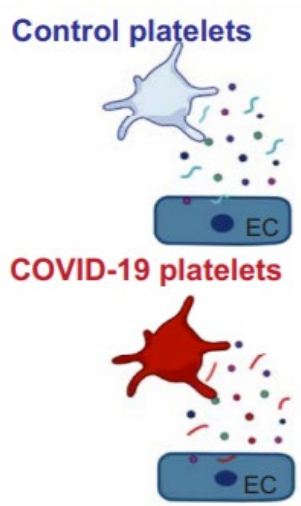


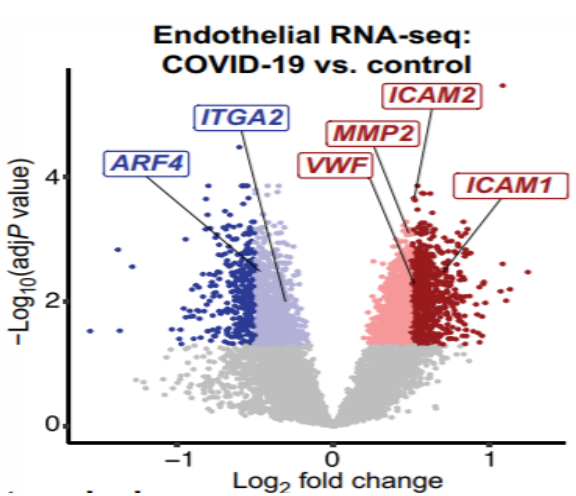


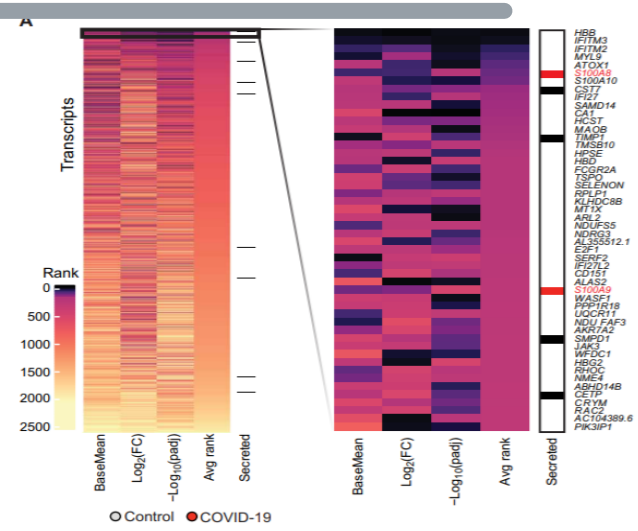












Demonstrated that platelet-derived factors promote an inflammatory hypercoagulable phenotype, and are significant contributors to poor clinical outcomes in COVID-19 patients

Testing anti-platelet agents

ACTIV-4HT: A Phase III Multicenter, Adaptive, Randomized Controlled Platform Trial of the Safety and Efficacy of RAAS and other HT-directed Agents in Hospitalized Adults with COVID-19

Prevention → Outpatient Asymptomatic → Outpatient Symptomatic → Emergency Department → **Hospital Vent/CPAP +** → **Hospital ICU** → Convalescence → Recovered

Patient Population: Moderately and severely ill adult hospitalized patients treated with oxygen for hypoxemia

Patients on O_2

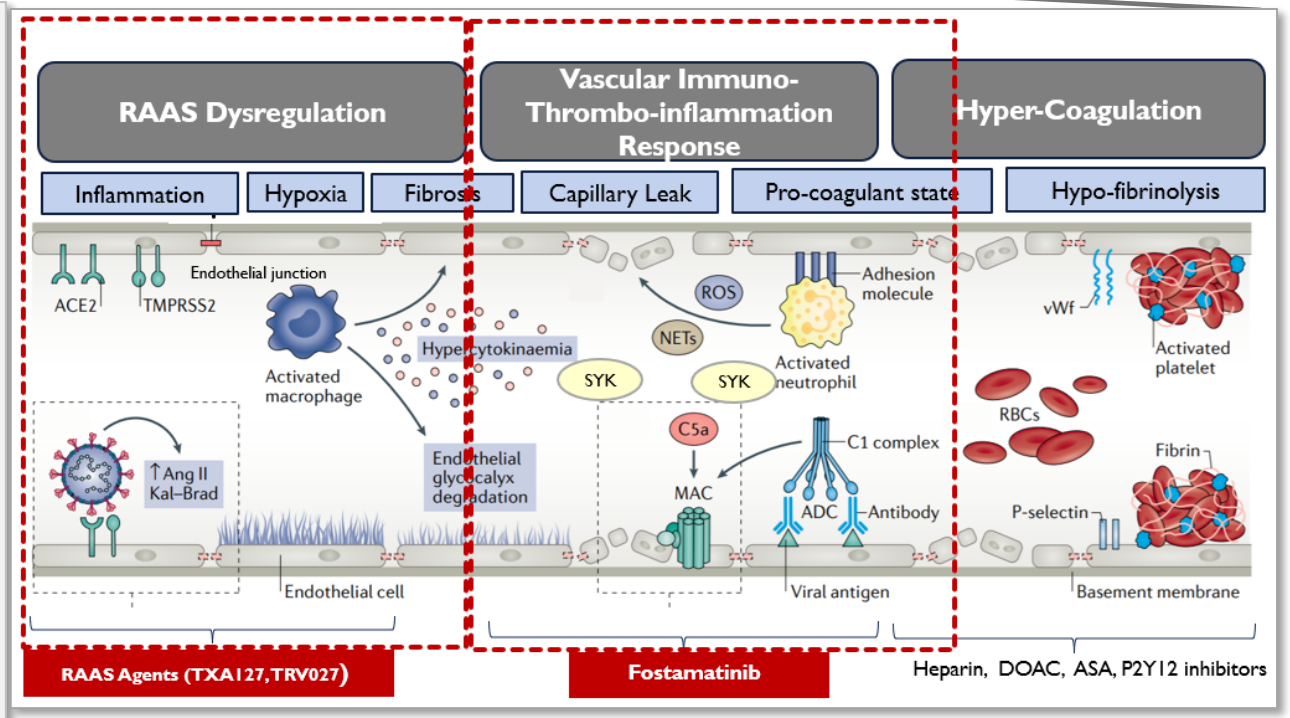
Interventions/Agents (Arms):

- Renin-Angiotensin-Aldosterone System (RAAS) Agents:
  - TXA127 and TRV027
- Inhibition of vascular inflammation:
  - Fostamatinib (spleen tyrosine kinase (SYK) inhibitor)
- Placebo

Target enrollment: 300 per arm

Primary Endpoint: Oxygen-free days from randomization through 28d

Secondary Endpoint: Mortality, WHO 8-point ordinal scale, support-free days through 28d



https://clinicaltrials.gov/ct2/show/NCT04924660?term=NCT04924660&draw=2&rank=1

Can RAAS-targeting agents and/or Fostamatinib prevent COVID-19 host-tissue responses: vascular injury, inflammation, fibrosis, capillary leakage, and thrombosis?

ACTIV-4HT: A Phase III Multicenter, Adaptive, Randomized Controlled Platform Trial of the Safety and Efficacy of RAAS and other HT-directed Agents in Hospitalized Adults with COVID-19

Prevention → Outpatient Asymptomatic → Outpatient Symptomatic → Emergency Department → **Hospital Vent/CPAP-free** → **Hospital ICU** → Convalescence → Recovered

Hospitalized Patients On Oxygen

Intervention: Fostamatinib (Spleen tyrosine kinase inhibitor)

Builds upon Phase II NHLBI study:

Clinical Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America · hivma hiv medicine association · OXFORD

Fostamatinib for the Treatment of Hospitalized Adults With Coronavirus Disease 2019: A Randomized Trial

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Phase II Trial of Fostamatinib: Safe in hospitalized patients requiring oxygen and associated w/ trend to clinical and biochemical improvement (esp. in severely ill patients)

CONNECTS

ACTIV-4B: COVID-19 Outpatient Thrombosis Prevention Trial: A Multi-center Adaptive Randomized Placebo-controlled Platform Trial Evaluating the Efficacy and Safety of Anti-thrombotic Strategies in COVID-19 Adults Not Requiring Hospitalization at Time of Diagnosis

Prevention | Outpatient Asymptomatic | **Outpatient Symptomatic** | **Emergency Department** | Hospital Vent/CPAP-free | Hospital ICU | Convalescence | Recovered

Clinically Stable Symptomatic Outpatients

JAMA | Original Investigation

Effect of Antithrombotic Therapy on Clinical Outcomes in Outpatients With Clinically Stable Symptomatic COVID-19

The ACTIV-4B Randomized Clinical Trial

JAMA November 2, 2021 Volume 326, Number 17

POPULATION

388 Women
269 Men

Outpatients with symptomatic COVID-19, platelet count >100 000/mm³, and estimated glomerular filtration rate >30 mL/min/1.73m²

Median age: 54 years

LOCATIONS

52
Sites in the US

INTERVENTION

657 Patients randomized
558 Patients analyzed

164	165	164	164
Aspirin	**Prophylactic apixaban**	**Therapeutic apixaban**	**Placebo**
81 mg/d + matching placebo for 45 days	2.5 mg twice/d for 45 days	5 mg twice/d for 45 days	Placebo twice/d for 45 days

PRIMARY OUTCOME

Composite of all-cause mortality, symptomatic venous or arterial thromboembolism, myocardial infarction, stroke, or hospitalization for cardiovascular or pulmonary cause

Anti-thrombotic prophylaxis (ASA, DOAC) is not indicated to reduce adverse cardiopulmonary outcomes in symptomatic but clinically stable COVID-19 outpatients

ACTIV-4C: A Phase III Multicenter, Adaptive, Randomized Platform Trial Evaluating the Safety and Efficacy of Antithrombotic strategies in COVID-19 Patients Following Hospital Discharge

Prevention → Outpatient Asymptomatic → Outpatient Symptomatic → Emergency Department → Hospital Vent/CPAP-free → Hospital ICU → **Convalescence** → Recovered

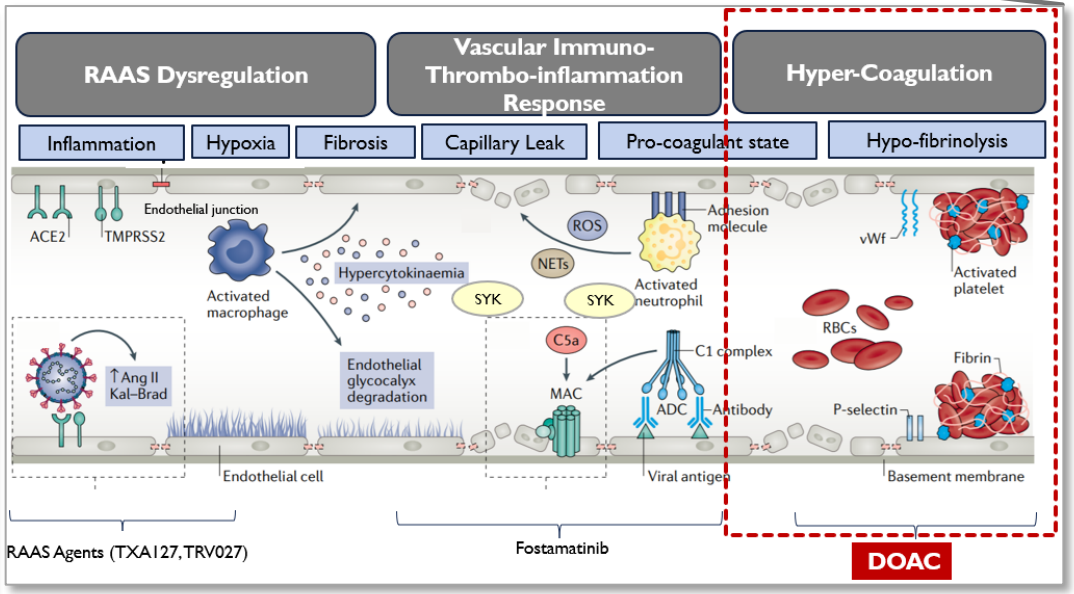
Intervention/Agent: Apixaban

Patient Population: Enrolling adults > 18 years of age with COVID-19 who are hospitalized ≥ 48 hours and ready for discharge

Primary Endpoint: Thrombotic Event; Binary composite endpoint of venous and arterial thrombotic complications and all-cause mortality

Secondary Endpoint: Individual outcomes of the composite primary endpoint, the time-to-event for the composite primary endpoint, and a clinical rank-based score

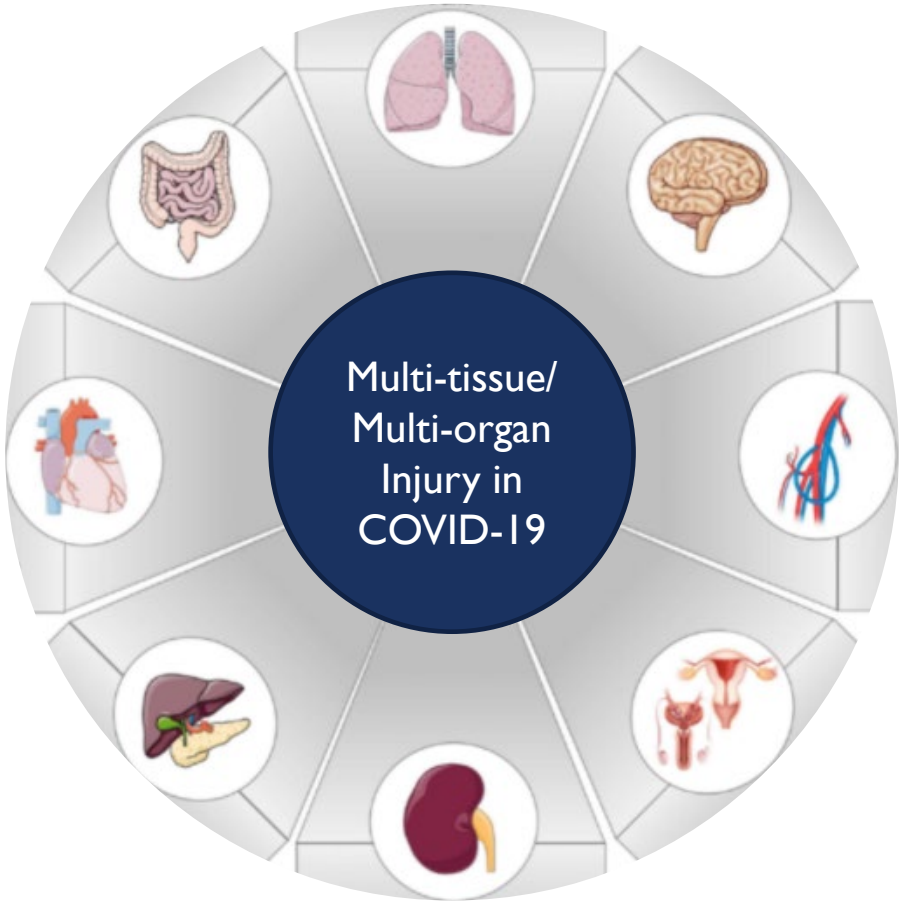
Clinicaltrials.gov: https://clinicaltrials.gov/ct2/show/NCT04650087



Can anti-thrombotic therapy in the post-acute setting prevent thrombo-embolic events and improve survival after hospital discharge?

Development of Host Tissue-Directed Therapeutics: Vital to Future Pandemic Preparedness

1. **Initial phase of a viral pandemic:** specific anti-viral agents (i.e. vaccines, anti-virals, or monoclonals) not readily available
2. **Later phases:** Even in presence of specific antiviral reagents, delays in effective protection to all components of the population
3. **Subsequent phase of a viral pandemic:** Pathogen evolves, is able to evade specific antigen recognition upon which vaccine and passive immunization strategies rely, and/or is able to circumvent mechanisms of, for example, specific protease inhibitors
4. **Post-acute infection phase** may be associated with significant host tissue sequelae which will require monitoring and development of therapeutic and prophylactic interventions



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Patients & Researchers
Policymakers & Govt Agencies
Academic Health Centers
International Organizations
Community Organizations
Primary Care
Private Sector
Professional Societies/ Foundations
Patients Citizen-Science
NIH
Thank you to Patients, Researchers, NIH and HHS Staff, for your critical role in improving COVID-19 therapies